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RESEARCH ARTICLE

Improvement in quality of life with buprenorphine in opioid dependence

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ABSTRACT

Background: The excessive opioid abuse leads to impaired quality of life (QOL) in opioid abusers. The data on the effect of oral substitution therapy (OST) on the QOL of opioid dependent are lacking from India. **Aims and Objectives:** This study aims to check the effect of OST on QOL of opioid abuser in Gurgaon for 6-month follow-up. **Materials and Methods:** A total of 202 patients with opioid dependent were taken for the study from a deaddiction center in Gurgaon. They received sublingual buprenorphine as oral substitution therapy and were assessed with Opiate Treatment Index (OTI) and Severity of Dependence Scale, at baseline, 1 month, 3rd month, and 6th month. Patients were also assessed with the World Health Organization QOL (WHOQOL) scale (Hindi version) at baseline, 3rd month, and 6th month to assess the improvement in QOL. **Results:** The significant improvement has been seen in OTI in opioid abuser 1 month onward and with regard to the WHOQOL-BREF scale scores, statistically significant *P* value has found for domain 2 (psychological) and domain 3 (social relationship) at 3rd and 6 months in heroin abuser. **Conclusion:** Improvement in QOL was seen with buprenorphine in patients of opioid dependence in Gurgaon.

KEY WORDS: Opioid; World Health Organization Quality of Life; Buprenorphine; Opiate Treatment Index

INTRODUCTION

The quality of life (QOL) in opioid abuse disorder could be defined in various ways such as side effects of medicine, influence of opioid abuse on body, social factors,[1,2] effect of treatment on patient,[3] and/or deaddiction management.[4,5] It also helps to find the results with different opioid substitution therapies.[6,7] QOL states to a person's awareness of their position in life in relation to their concern, standards, goals, and expectations.[8] Improvement in QOL is widely considered as an important outcome in treatment[9,10] which is lagging behind in patients with opioid dependence. Abstinence and reduction of opioids with other drugs abuse are generally considered primary measures of treatment success in opioid dependence.[11] Very few opioid-dependent patients attain continued abstinence[12] and sustained drug use is not certainly an indicator of poor QOL.[13] Mainly, it is decreased QOL that push an opioid addict to initiate treatment uptake rather than a wish to reduce drug use *per se*.[14] QOL could be increased with sustain abstinence.[15,16] The person with opioid dependent have more dysfunction in their life.[17] Majority of studies on the effect of oral substitution therapy (OST) for opioid dependence on QOL are from the developed countries.[18,19] There are lot of available choices for the management of opioid dependence, which include agonists methadone, buprenorphine, opioid antagonist naltrexone, or alpha-2 agonist clonidine.[20] Around the world, buprenorphine and methadone are two well-established opioid agonists for treatment in opioid dependence.[21] In India, only buprenorphine is available over the counter for opioid

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dependence, but there are very few studies that have been done to show its effect on the QOL.[22] QOL can be measured by a various instruments.[23] The Hindi version of the WHO QOL scale is established in India and is readily available.[24] In the current study, we assessed the improvement in QOL with buprenorphine in patients of opioid dependence in Gurgaon.

MATERIALS AND METHODS

It was an observational study which was conducted at licensed deaddiction centers in Haryana and the study was conducted in outpatient department (OPD) of the center. The study was done from January 2016 to December 2017. The patients who visited the center with opioid dependence were taken into the study after the written consent. A total of 202 patients with opioid dependence were enrolled in the study. For the study purpose, patients between the age of 18 years and 65 years of either gender, diagnoses with symptomatic opioid dependent as per the International Statistical Classification of Diseases-10 criteria,[25] who ready to give consent for the interview or willing to participate in the study were included in the study. Patients who had any serious medical conditions such as respiratory disorders, liver disorders, alcohol dependence syndrome, and pregnant or lactating female, patients who had allergy to buprenorphine or who had previous or present history of major mental or medical disorders due to patient were not able to take part in study, were excluded from the study. In the center, patients were treated by respective deaddiction specialist and assessor had no involvement in the treatment. After prescribing treatment for opioid dependence, patient's prescription was assessed by assessor to assess the pattern of medication prescribed. After taking the written consent, patients were assessed with Opiate Treatment Index (OTI)[26] and Severity of Dependence Scale (SDS),[27] at baseline, 1 month, 3rd month, and 6th month. Patients were also assessed with the WHO QOL scale (Hindi version)[24] at baseline, 3rd month, and 6th month to assess the improvement in QOL.

Dosage: The patients were put on buprenorphine on flexible dose range. The treating psychiatrist prescribed the buprenorphine dose on the basis of current opioid abuse, desire, and withdrawal symptoms. The buprenorphine dosage range (2–10 mg/day) was required for the maintenance of opioid dependence.

Statistical Analysis

The data were collected by the investigator at the center only. All questionnaires were assessed for comprehensiveness. SPSS version 21.0 was used to assess the data. Sociodemographic profile such as age, sex, education, income, marital status, and employment status was described and assessed with Chi-square for categorical variable. The four domains of QOL scale were used to assess the improvement of QOL in opioid addicts. Spearman's rho was used to check the correlation.

RESULTS

The comparison of sociodemographic profile of patients in Gurgaon is mentioned in Table 1. Their sociodemographic profile did not show any significant finding [Table 1].

Table 2 has showed the score of drug use in Opiate Treatment Index (OTI). Drug use index gives information about the exposure of respective opioid in the past few days. Patients have showed significant improvement after 1 month of treatment. After 1 month of exposure of treatment, mean score of 51 of heroin abusers (3.29) has significantly come down to 0.38 which has further decreased to 0.4 to at the end of 6th month follow-up. The number of patients who took heroin has also decreased after 1 month onward. Similar results have been observed in patients with opium abuse and capsule Proxyvon. Patients with opium abuser have significantly decreased from 146 at the baseline to 10 within 1 month of treatment, and in case of capsule Proxyvon, number has further reduced to 1 from 5 within 1 month of treatment.

Table 3 has showed the crime index component of OTI at baseline, 1 month, 3rd month, and 6th month. It shows the decrease in number of patients on crime index, i.e., number of patients with scores more than 1, but the results are non-significant. At the baseline, a total of 45 patients with opioid dependence, who have score more than one and with treatment patients with crime index, have decreased to 10 till the end of 6 months.

Table 1: Comparison of sociodemographic characteristic of patients in Gurgaon

Variables	Haryana (*n*=202)
Age	39.113±8.311
Sex (male), *n* (%)	202 (100)
Education, *n* (%)	
Illiterate	32 (15.84)
Metric	91 (45.05)
Intermediate	47 (23.27)
Graduate	32 (15.84)
Income (per month), *n* (%)	
<Rs. 3500	62 (30.69)
Rs. 3500–7000	56 (27.72)
>Rs. 7000	84 (41.59)
Employment status, *n* (%)	
Employed	174 (86.14)
Unemployed	28 (13.86)
Marital status, *n* (%)	
Married	164 (81.19)
Unmarried	20 (9.90)
Divorced or separated	18 (8.91)

Table 4 has showed the SDS at baseline, 1 month, 3rd month, and 6th month. It has showed significant improvement in heroin abuser 1 month onward. Scores have also decreased in opium and capsule Proxyvon abuser, but results are non-significant.

Table 5 has showed *P* value after comparison between heroin opium and capsule Proxyvon at each assessment. With regard to the World Health Organization QOL-BREF (WHOQOL-BREF) scale scores, statistically significant *P* value has found for domain 2 (psychological) and domain 3 (social relationship) at 3rd and 6 months in heroin abuser. All domains of QOL have showed statistically significant results at 6 months in heroin abuser.

Around 26% of patients dropped out of the study and did not complete 6 months of treatment. Most of them left treatment in initial phase of the study. We do not have the reason behind the drop out of the study. None of the patients had a history of buprenorphine treatment and few of the patients had heard of the medication. Retention rate in all our study was around 73.77%.

DISCUSSION

In the current study, buprenorphine was the only oral substitution therapy used by treating psychiatrist in deaddiction OPD. All the patients were assessed with Opiate Treatment Index (OTI) on different subdomains such as drug use, social functioning, criminality, health status, and psychological adjustment. The significant improvement has been seen in OTI in opioid abuser 1 month onward and with regard to the WHOQOL-BREF scale scores, statistically significant *P* value has found for domain 2 (psychological) and domain 3 (social relationship) at 3rd and 6 months in heroin abuser.

As in India, methadone is not available over the counter, so all the patients were managed on buprenorphine.[28] The average drug abuse with buprenorphine decreased from 2 to 3 times a day to less than once in 3 days in heroin abuser and less than once a week in bhukki or capsule Proxyvon abuser. Similar finding, we had seen in another study done by National Deaddiction Center AIIMS (NDDC AIIMS), in which mean days of heroin used were reduced from 24.1 days

Table 2: Opiate Treatment Index (drug use) at baseline, 1st month, 3rd month, and 6th month

Variables	Baseline	1st month	3rd month	6th month
Heroin abuser	*n*=51 3.29±0.944	*n*=51 0.38±0.263	*n*=17 0.065±0.039	*n*=7 0.04±0.021
P value		0.001	0.001	0.001
Opium/doda abuse	*n*=146 2.35±0.633	*n*=10 0.05±0.020	*n*=1 0.03±0.010	*n*=1 0.02±0.003
P value		0.001	0.001	0.001
Capsule Proxyvon abuser	*n*=5 3.5±0.836	*n*=1 0.08±0.181	*n*=0 0	*n*=0 0
P value		0.001	0.001	0.001

P<0.001, *P*<0.05

Table 3: Variable on Opiate Treatment Index (crime index) at baseline, 1st month, 3rd month, and 6th month

Variables	Baseline (%)	1st month (%)	3rd month (%)	6th month (%)	*P*-value
Total	45 (22.27)	28 (13.86)	21 (10.40)	10 (4.95)	0.078
Heroin abuser	37 (82.22)	25 (89.29)	18 (85.72)	7 (70)	0.271
Opium/doda abuse	3 (6.67)	1 (3.57)	1 (4.76)	1 (10)	0.982
Capsule Proxyvon abuser	5 (11.11)	2 (7.14)	2 (9.52)	2 (20)	0.829

**P*<0.001, **P*<0.05

Table 4: Comparison on severity of dependence scale at baseline, 1st month, 3rd month, and 6th month in Haryana

Variables	Baseline	1st month	3rd month	6th month
Heroin abuser	11.75±1.362	0.71±0.452**	0.52±0.325**	0.41±0.231**
P value		0.001	0.001	0.001
Opium/doda abuse	4.52±1.861	0.46±0.161	0.32±0.283	0.21±0.192
P value		0.972	0.498	0.275
Capsule Proxyvon abuser	4.0±0.707	0.21±0.131	0.19±0.142	0.14±0.118
P value		0.317	0.171	0.087

**P*<0.001, **P*<0.05

Table 5: Comparison on the World Health Organization quality of life at baseline, 1st month, 3rd month, and 6th month

Domain	Haryana											
	Heroin	Opium	Capsule Proxyvon	Heroin	Opium	Capsule Proxyvon	Heroin	Opium	Capsule Proxyvon	Heroin	Opium	Capsule Proxyvon
	Baseline			1st month			3rd month			6th month		
Domain 1 (physical)	36.65±9.352	65.01±9.125	64.02±8.171	38.85±10.743	65.49±9.782	64.52±8.927	57.23±7.172	66.21±8.215	69.02±8.171	65.4*3±6.237	69.32±8.172	71.12±8.251
P value				0.907	0.981	0.816	0.325	0.272	0.281	0.043	0.117	0.189
Domain 2 (psychological)	30.26±7.261	54.87±6.152	50.21±5.716	31.35±8.527	55.23±6.526	50.35±5.456	58.2*3±8.217	58.78±7.182	61.91±6.129	67.2*9±8.819	68.88±8.821	61.91±6.132
P value				0.819	0.751	0.915	0.05	0.381	0.213	0.033	0.127	0.211
Domain 3 (social)	32.04±7.715	62.13±7.152	44.12±7.717	32.93±7.237	63.73±7.829	44.25±7.819	57.2*1±8.191	66.10±8.615	59.71±8.142	67.1*2±8.172	65.12±8.635	66.23±8.281
P value				0.961	0.561	0.891	0.049	0.179	0.114	0.023	0.161	0.098
Domain4 (environment)	35.162±8.171	65.21±7.132	47.17±6.124	36.46±8.390	66.91±7.201	48.29±6.167	55.91±8.162	67.51±8.651	55.91±5.512	64.1*0±7.182	69.23±8.521	65.12±6.827
P value				0.813	0.727	0.618	0.081	0.161	0.106	0.013	0.090	0.089

P<0.001, *P*<0.05

to <2 days.[29] Similar finding, we have seen in a study done by Mohan *et al.*, in Nagaland, where buprenorphine showed a significant decrease in drug use in opioid-dependent patients.[30] The crime index of OTl assessed the involvement of drug-induced criminal activity such as fraud, crime involving violence, property crime, and drug peddling. Most of the criminal activity was seen in patients with heroin abuse as compared to bhukki or capsule Proxyvon. Similar finding was seen in one of the studies done in Baltimore metropolitan area, where 354 heroin abusers were assessed with OTI crime index and high level of criminality, around 255 composite crime days per year, was seen.[31] Most of the heroin abusers were in criminal activity and this could be due to legal and financial implication with the heroin abuse. In our study, patients after prescribing the oral substitution therapy showed decrease in involvement in crime activity. This result was in favor of one of the longitudinal studies, where reduction in crime was seen after opioid maintenance therapy,[32] but this finding was against one study, in which no significant impact was seen on criminal charges on maintaining patients on office-based buprenorphine.[33] After taking oral substitution therapy, patients in all states showed improvement in the entire domains of the WHO QOL-BREF scale. As compared to bhukki abuser, heroin abuser had very low score in the WHO QOL-BREF scale. This could be due to physical and psychological deterioration seen in heroin abuser. Similar finding, we had seen in one of the studies done by Fassino *et al.* where heroin abuser has had low score on McGill QOL scale in all the domains.[34] In our study, we had seen significant improvement in QOL in heroin abuser after the 3rd month onward. Similar finding, we had seen in the study conducted by NDDC AIIMS, where patients showed improvement in all the domains of QOL after taking buprenorphine. In the current study, opioid-dependent patients showed improvement with tablet buprenorphine. It could be due to improvements in the physical symptoms with buprenorphine therapy. The changes in the scores in different domains of QOL show the effect of OST on the different domains. The evidence from the previous study shows that that giving the good psychosocial support with the treatment leads to improvement in drug-related problems,[35] treatment response, and abstinence[36] which leads to better life quality. Improvement of QOL could be due to decrease in severity of drug dependence. After beginning of the treatment, patients showed decrease in dependence on their respective abuse [Table 4]. Similar finding was seen in a study conducted by Kakko *et al.*,[37] in Sweden, where social function and retention rate with buprenorphine were far better than placebo due to decrease in severity of drug dependence. The retention rate of the current study was 73.77%. Similar finding was seen in a study done in Manipur and Nagaland,[30] the WHO collaborative study that included locations from low-, middle-, and high-income countries.[38] The good retention rate was evidently important for the successful OST programs. As the findings from this research and other studies show that longer the retention with OST program,

the better the likelihood that patients would complete the program.[39] Other studies had reported that higher dosage of buprenorphine is an important determinant of retention in the treatment program.[40]

As our study was the first study of its kind in India to assess the effect of buprenorphine on QOL on opioid dependent, still our study had certain limitations. As we did not check the dose of patients, so we could not correlate the improvement and retention rate on the basis of dosage. As this was the observational study, so observer bias could not be ruled out. The number of patients with capsule Proxyvon dependence was very less, so selection bias cannot be ruled out.

CONCLUSION

We conclude that buprenorphine has showed a significant effect on QOL of opioid abusers. This result must help to plan further study and policy for the use of buprenorphine in opioid dependence in India.

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